DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Synthes USA
Mr. Nicholas Fountoulakis
Regulatory Affairs Specialist
1301 Goshen Parkway
West Chester, Pennsylvania 19380

March 30, 2015

Re: K141527
Trade/Device Name: DePuy Synthes Variable Angle Locking Hand System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: February 18, 2015
Received: February 19, 2015

Dear Mr. Fountoulakis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
DePuySynthes Variable Angle Locking Hand System

Indications for Use *(Describe)*
The DePuy Synthes Variable Angle Locking Hand System is intended for fracture fixation of the hand and other small bones and small bone fragments, in adults and adolescents (12-21) particularly in osteopenic bone.

System indications include the following:
- Open reduction and internal fixation of fractures, mal-unions, and non-unions
- Following excision of benign bone tumors
- Replantations and reconstructions
- Arthrodeses of joints involving small bones
- Osteotomies, including deformity correction such as rotation, lengthening, shortening
- Pathological fractures, including impending pathologic fractures

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Date Prepared: March 16, 2015

Sponsor:	DePuy Synthes Nicholas Fountoulakis 1301 Goshen Parkway West Chester, PA 19380 Office: (610) 719-6553 Fax: (484)-356-9682
Proprietary Name:	DePuy Synthes Variable Angle Locking Hand System
Classification:	Classification: §888.3030, §888.3040 Product Code: HRS, HWC
Predicate Device:	Synthes 1.5mm LCP Mini-Fragment System (K090047) Synthes Locking Hand Plates (K092247) Synthes Stainless Steel Modular Hand System (K030310) Synthes VA Locking Screws (K100776, K120689, K110354)
Device Description:	The DePuy Synthes Variable Angle Locking Hand System consists of metallic plates and screws that offer screw-to-plate locking designed for various fracture modes of the hand. Generally, the system consists of plates, screws, and instruments which feature variable angle locking technology. The plates contained in the DePuy Synthes Variable Angle Locking Hand System are offered in a range of configurations to accommodate patient anatomy and surgical need. The plates are designed to accept existing 1.5mm cortex screws (K090047), previously cleared 1.5mm Locking Screws at the nominal angle only (K090047), and new 1.5mm VA Locking Screws. The new 1.5mm VA Locking Screws feature existing variable angle locking technology (K100776, K120689, K110354), and are designed to fit in the 1.5mm holes of the subject plates.

Indications for Use:	The DePuy Synthes Variable Angle Locking Hand System is intended for fracture fixation of the hand and other small bones and small bone fragments, in adults and adolescents (12-21) particularly in osteopenic bone. System indications include the following: • Open reduction and internal fixation of fractures, mal-unions, and non-unions • Following excision of benign bone tumors • Replantations and reconstructions • Arthrodeses of joints involving small bones • Osteotomies, including deformity correction such as rotation, lengthening, shortening • Pathological fractures, including impending pathologic fractures
Substantial Equivalence:	The proposed DePuy Synthes Variable Angle Locking Hand System shares the same fundamental technological characteristics as the predicate systems (K090047, K092247, K100776, K120689, and K110354). Non-Clinical information has been provided in support of the performance of the subject system as follows: • Finite Element Analysis to determine worst case constructs • Dynamic Fatigue Testing on representative constructs • Torsional properties of 1.5mm VA Locking Screws per ASTM F543 • Pullout strength of 1.5mm VA Locking Screws per ASTM F543 • Insertion Torque of 1.5mm VA Locking Screws per ASTM F543 Literature has been provided to support the revision in indications, including the addition of the adolescent population. The same technologies are used across the subject and predicate systems through features such as Combi-holes, limited contact profiles, variable and standard locking technology, anatomic contours, and similar size ranges. Based on the presented comparisons and discussions, the subject DePuy Synthes Variable Angle Locking Hand System does not raise any new issues of safety and efficacy.